

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12980



2 - LABEL SAMPLE

000001

PERCENTAGE OF U.S. RECOMMENDED DAILY ALLOWANCES

| | 1 level scoop 28.4 g / 1 oz | For serving size of 1 scoop |
|----------------------------|--------------------------------|--|
| 1 size is per container | 16 | 7 g |
| 5 | 101 | Vitamin A 2900 IU |
| hydrates | 16 g | Vitamin B ₁ (thiamine) 70 mg |
| itol | 1 g | Vitamin B ₂ (riboflavin) 10 mg |
| | 0 | Calcium 200 mg |
| | 75 mg | Iron 360 mg |
| 1. 15% sodium | 220 mg | Vitamin D 35 IU |
| | | Vitamin E 30 IU |
| | | Vitamin K 60 mcg |

Phosphorous
Iodine[illegible]

415 mg

| AMINO ACIDS | |
|-----------------|---------------|
| L-threonine | [BCAA] 640 mg |
| L-serine | [BCAA] 365 mg |
| L-valine | [BCAA] 261 mg |
| L-lysine | 478 mg |
| L-threonine | 428 mg |
| L-methionine | 129 mg |
| L-phenylalanine | 211 mg |
| L-tyrosine | 98 mg |

All complete proteins contain L-tyrosine. No manufactured L-tyrosine has been added.

All complete proteins contain L-tryptophan. No manufactured L-tryptophan has been added.



Made with pride in the USA

A product from
NEXT NUTRITION
Science for Muscles
P O Box 2469
Carlsbad, CA 92018
Entire label contents
© Next Nutrition 1992



ULTIMATE

WORKOUT DRINK MIX • SINCE 1982



WORKOUT DRINK MIX • SINCE 1982

FLAWLESS

ORANGE

NET WEIGHT 1 LB (454 G)

Here it is —
Ultimate Orange™

The most powerful workout driver ever developed.

One serving of **Ultimate Orange** and you'll difference. It's like no other drink available today. **Ultimate Orange** contains a proprietary blend of nutrients and 14 hard working muscles. It is the perfect drink to use before and during workouts when you need maximum energy.

WHEN TO DRINK
ULTIMATE ORANGE™

Before exercise — Drink one serving for body weight 30 ' prior to exercise

During exercise — Take sips between laps or sets or every 15 minutes throughout workout. Avoid gulps all at once.

For extra energy — Drink one serving for body weight 30 minutes before you feel tired.

**HOW MUCH
ULTIMATE ORANGE™
TO DRINK**

Follow the table below as guideline of usage amounts versus body weight. A person has a unique metabolism that may require a slightly smaller or larger size for preferred effects.

| Bodyweight | lbs | kgs |
|------------|---------|---------|
| 132 | 154 | 176 |
| 60 | 70 | 80 |
| 1/2 | 1/2-3/4 | 1 |
| | | 1-1 1/2 |

MIXING INSTRUCTIONS

Place 1 level scoop in glass, add 8 fl oz / 1 cup water. Stir.

Ultimate Orange mixes quickly with a few stirs.

There is no need for a blender.

To fill 16 fl oz water bottle — place 2 scoops in water bottle, half fill & shake vigorously and then fill to top with water

ATTENTION ALL ATHLETES: ANYONE SUBJECT TO DRUG-TESTING DURING COMPETITION MUST FOLLOW THE FOLLOWING DOPING CONTROL PROCEDURES UNDER IOC, USOC, NCAA, AND OTHER DOPING AGENCIES. IF YOU ARE A DOPED ATHLETE, YOUR RULES SHOULD CEASE USING THIS PRODUCT AT LEAST 5 DAYS BEFORE PROVIDING URINE SAMPLES.

Important Notice: Seek advice from a health care practitioner prior to use if you are pregnant or nursing, or if you have high blood pressure, heart or liver disease, diabetes, difficulty in urination due to prostate enlargement, or if taking inhibitors or any other prescription drug. Bedipne® or discontinuation (use) of the product may cause dizziness, lightheadedness, or fainting. If you experience tremor, sleeplessness, loss of appetite or nausea occur. Not for use in children. **KEEP OUT OF REACH OF CHILDREN**

© 1997 by The McGraw-Hill Companies, Inc.

**NUTRITIONAL
INFORMATION
PER SERVING**

1 level scoop
Serving size.....28.4g/1 oz.
Servings per container.....16
Calories.....101
Protein.....7 g
Carbohydrates.....16 g
Fat.....1 g
Cholesterol.....0
Sodium.....15 mg
Potassium.....220 mg

INGREDIENTS

QUADRACARB [4 stage release carbohydrate from branching chain glucose polymers from amylopectins, high glycemic index maltose with dextrose, plus low glycemic index fructose], LACTOPRO [high biological value, low lactose Lactoglobulin, Lactalbumin, Lactoferrin and Immuglobulin protein fractions from enzymatically treated and filtered, low fat, whey protein concentrate, BioVite [bioactive vitamin-mineral blend of potassium phosphate, calcium carbonate, magnesium oxide, zinc gluconate, potassium succinate, vitamin E acetate, ascorbic acid, calcium pantothenate, choline, inositol, molybdenum aspartate, selenium aspartate, manganese gluconate, ferrous fumarate, boron tri-citrate-aspartate-glycinate, potassium iodide, retinyl palmitate, pyridoxine HCl, niacin, riboflavin, thiamine, chromium arginate, biotin, ergocalciferol, cyanocobalamin, betacarotene, ferrous succinate, chromium picolinate], citric acid,

ULTIMATE ORANGE HERBAL CONCENTRATE

[a proprietary herbal powder blend from Ma Huang, Guarana Seed, Green Tea, Siberian Ginseng, and Bioflavonoids from orange peel], Structured Lipid Complex [medium chain triglycerides with omega-3 fatty acids], Xylitol, natural flavors, lecithin, cellulose gum, xanthan gum, food coloring.

Store in a cool dry place out of direct sunlight.
Like all naturally derived products, appearance may differ slightly from one batch to another.
A free measuring scoop is included in this container.
This product is packed by weight and not volume.
Some settling of the contents will have occurred during transportation.

[bar code symbol]

**PERCENTAGE OF U.S.
RECOMMENDED DAILY
ALLOWANCES**

For serving size of 1 scoop %
Protein.....7 g.....15
Vitamin A.....2500 iu.....50
Vitamin C.....50mg.....80
Vitamin B₁ [thiamin].....70 mcg.....50
Vitamin B₂ [riboflavin].....85 mcg.....50
Niacin.....10 mg.....50
Calcium.....200 mg.....20
Iron.....360 mcg.....20
Vitamin D.....56 iu.....15
Vitamin E.....30 iu.....80
Vitamin B₆.....8 mg.....400
Folic acid.....200 mcg.....50
Vitamin B₁₂.....5 mcg.....80
Phosphorus.....175 mg.....15
Iodine.....70 mcg.....50
Magnesium.....140 mcg.....30
Zinc.....12 mg.....50
Copper.....260 mcg.....15
Biotin.....140 mcg.....50
Pantothenic acid.....40 mg.....400
Chromium.....25 mcg.....**
Molybdenum.....30 mcg.....**
Selenium.....20 mcg
Manganese.....2 mg
Choline.....75 mg
Inositol.....75 mg
Ma Huang [ephedra].....415 mg

**ESSENTIAL
AMINO ACIDS**

L-leucine.....[BCAA].....640 mg
L-isoleucine...[BCAA].....365 mg
L-valine.....[BCAA].....261 mg
L-lysine.....478 mg
L-theonine.....428 mg
L-methionine.....129 mg
L-phenylalanine.....211 mg
L-tryptophan.....98 mg
All complete proteins contain L-tryptophan.
No manufactured L-tryptophan has been added.

[logo]
Made with pride in the USA

A product from
NEXT NUTRITION
Science For Winning
P.O. Box 2469
Carlsbad, CA 92018

Entire label contents
© Next Nutrition 1992

000003

*Verified by
Janet Burke 7/16/98*

Here it is –

Ultimate Orange™

The most powerful workout drink
ever developed.

One serving of **Ultimate Orange** and you'll feel the
difference. It's like no other drink available today. **Ultimate
Orange** contains a proprietary blend of nutrients and herbs for
hard working muscles. It is the perfect drink to use before and
during workouts when you need maximum energy.

[logo] **WHEN TO DRINK
ULTIMATE ORANGE™**

Before exercise – Drink one serving for body weight 30-45 minutes
prior to exercise.

During exercise – Take sips between reps or sets or every 15-20 minutes
throughout workout. Avoid gulps all at once.

For extra energy – Drink one serving for body weight 30 minutes before
you feel tired.

[logo] **HOW MUCH
ULTIMATE ORANGE™
TO DRINK**

Follow the table below as guideline of usage amounts versus body weight. Each
person has a unique metabolism that may require a slightly smaller or larger serving
size for preferred effects.

| | | | | | | |
|------------------|-----|-----|---------|-----|---------|-------|
| Bodyweight | lbs | 132 | 154 | 176 | 198 | 220 |
| | kgs | 60 | 70 | 80 | 90 | 100 |
| Number of scoops | | 1/2 | 1/2-3/4 | 1 | 1-1 1/2 | 1 1/2 |

[logo] **MIXING INSTRUCTIONS**

Place 1 level scoop in glass, add 8 fl.oz./1 cup water stir and drink.

Ultimate Orange mixes quickly with a few stirs of a spoon.

There is no need for a blender.

To fill a 16 fl.oz. water bottle – place 2 scoops in water bottle, half fill with water,
shake vigorously, and then fill to top with water.

**ATTENTION ALL ATHLETES: ANYONE SUBJECT TO DRUG-TESTING OR
DOPING CONTROL PROCEDURES UNDER IOC, USOC, NCAA, IPC, IFBB
RULES SHOULD CEASE USING THIS PRODUCT AT LEAST 5 DAYS BEFORE
PROVIDING URINE SAMPLES.**

Important Notice: Seek advice from a health care practitioner prior to use. If you
are pregnant, or nursing, or if you have high blood pressure, heart or thyroid disease,
diabetes, difficulty in urination due to prostate enlargement, or if taking an MAO
inhibitor or any other prescription drug. Reduce or discontinue use if nervousness,
tremor, sleeplessness, loss of appetite or nausea occur. Not for children under 13.
KEEP OUT OF REACH OF CHILDREN.

“This is not a product of the Ultimate Juice Company, Inc.”

© Next Nutrition 1992

000004

*Verified by
Janet Burke
7/16/98*

Sample Labeling
Ultimate Orange

15533 (98904229)
JLBussey

Here it is –

Ultimate Orange™

The most powerful workout drink
ever developed.

One serving of **Ultimate Orange** and you'll feel the
difference. It's like no other drink available today. **Ultimate
Orange** contains a proprietary blend of nutrients and herbs for
hard working muscles. It is the perfect drink to use before and
during workouts when you need maximum energy.

[logo] **WHEN TO DRINK
ULTIMATE ORANGE™**

Before exercise – Drink one serving for body weight 30-45 minutes
prior to exercise.

During exercise – Take sips between reps or sets or every 15-20 minutes
throughout workout. Avoid gulps all at once.

For extra energy – Drink one serving for body weight 30 minutes before
you feel tired.

[logo] **HOW MUCH
ULTIMATE ORANGE™
TO DRINK**

Follow the table below as guideline of usage amounts versus body weight. Each
person has a unique metabolism that may require a slightly smaller or larger serving
size for preferred effects.

| | | | | | | |
|------------------|-----|-----|---------|-----|---------|-------|
| Bodyweight | lbs | 132 | 154 | 176 | 198 | 220 |
| | kgs | 60 | 70 | 80 | 90 | 100 |
| Number of scoops | | 1/2 | 1/2-3/4 | 1 | 1-1 1/2 | 1 1/2 |

[logo] **MIXING INSTRUCTIONS**

Place 1 level scoop in glass, add 8 fl.oz./1 cup water stir and drink.

Ultimate Orange mixes quickly with a few stirs of a spoon.

There is no need for a blender.

To fill a 16 fl.oz. water bottle – place 2 scoops in water bottle, half fill with water,
shake vigorously, and then fill to top with water.

**ATTENTION ALL ATHLETES: ANYONE SUBJECT TO DRUG-TESTING OR
DOPING CONTROL PROCEDURES UNDER IOC, USOC, NCAA, IPC, IFBB
RULES SHOULD CEASE USING THIS PRODUCT AT LEAST 5 DAYS BEFORE
PROVIDING URINE SAMPLES.**

Important Notice: Seek advice from a health care practitioner prior to use. If you
are pregnant, or nursing, or if you have high blood pressure, heart or thyroid disease,
diabetes, difficulty in urination due to prostate enlargement, or if taking an MAO
inhibitor or any other prescription drug. Reduce or discontinue use if nervousness,
tremor, sleeplessness, loss of appetite or nausea occur. Not for children under 13.
KEEP OUT OF REACH OF CHILDREN.

"This is not a product of the Ultimate Juice Company, Inc."

FORM

© Next Nutrition 1992

000005

*Verified by
Janet Burke
7/16/98*

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN HFS-452
98 JUL 21 P 2:25

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 15533

| | | | | | |
|------------------|----------------|-------------------|------------------|--------|-------|
| Flag | Basis | Sample Type | FIS Smpl Num | | |
| Complaint Sample | Surveillance | Investigational | 98904229 | | |
| FEI | Date Collected | Product Code | Responsible Firm | PAC | Hours |
| | 30-JUN-98 | 54YCR99 | Dealer | 03R801 | 14 |
| Related Smpl Num | Position Clas | Sampling District | | | |
| | INS | LOS-DO | | | |

Product Description

LIGHT POWDER IN A FOIL LINED PAPER CANISTER WITH A PLASTIC SNAP ON LID.

Product Label

"NEXT NUTRITION ULTIMATE ORANGE NET WEIGHT 1 LB (454G) P.O. BOX 2469 Carlsbad, CA 92018"

Reason for Collection

SAMPLE COLLECTED AS PER CFSAN ASSIGNMENT
PROJECT #12980 DTD.6/23/98, TO DETERMINE THE
EPHEDRINE LEVELS.

MFG Codes

19913712 M34373567-12

Expiration Date

Firm Legal Name

NEXT NUTRITION

Address

6231 YARROW DR CARLSBAD, CA US

Type of Firm

Manufacturer

Size of Lot

UNK

Est. Value

\$20

Rcpt Type

FDA484

Date Shipped & Doc. Ref.

06/30/1998

Description of Sample

CONSUMER'S SAMPLE OF ULTIMATE ORANGE IN A PAPER/FOIL CANISTER WITH A PLASTIC SNAP ON LID.

Method of Collection

Sample was obtained from [REDACTED] on the quarterdeck. Dr. [REDACTED] left the canister in [REDACTED] charge, until pick-up.

How Prepared

1-1 lb opened canister collected from consumer and sealed. FD-525 attached.

Collector's Identification on Package and/or Label

"98-15533 6/30/98 dyh"

Collector's Identification on Seal

"98-15533 6/30/98 DAVID Y. HERNANDEZ"

Sample Delivered To

SEA-DO

Dated Deliverd

06/30/1998

Orig C/R & Records To

LOS-DO

Lab w/Split Sample

0

Lab

SEA-LAB

Document Number

Document Date

06/24/1998

Document Type

Other

Remarks

SAMPLE COLLECTED FROM DR. [REDACTED] OFFICE ON THE BASE.

Payment Amount

\$0

Payment Method

No Charge

704(d) Sample

No

Collector's Name

David Y Hernandez

Name of Signer

David Y Hernandez

Date & Time of Signature

06/30/1998 07:48 PM

Meaning

Collector

98 JUL -8 P12:24

Date: 06/30/1998

Page: 1 of 1

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN HFS-452

000006

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSK/HS-452